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DLA PIPER US LLP ATTN: PATENT GROUP 1200 NINETEENTH STREET, NW WASHINGTON, DC 20036			EXAMINER OH, SIMON J	
			ART UNIT	PAPER NUMBER
			1618	

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 09/671,106  
Filing Date: September 28, 20009  
Appellant(s): BUDDINGTON ET AL.

**MAILED  
FEB 26 2007  
GROUP 1600**

James M. Heintz and Ping Wang, M.D.  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 01 November 2006 appealing from the Office action  
mailed 27 February 2006.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

6,241,983	PAUL et al.	6-2001
6,500,805	VAN LOO et al.	12-2002

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

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Claims 18-20, 23, 24, 27, 30, 31, 33, 34, 37, and 41-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Paul *et al.* and Van Loo *et al.*

The Paul *et al.* patent teaches an orally administered composition for promoting gastrointestinal health comprised of an effective amount of dietary fiber (See Abstract; and Column 3, Lines 39-57). The dietary fiber is a member selected from the group consisting of fructo-oligosaccharides, such as inulin, pectins, pectic polysaccharides, and mannans such as guar gum (See Column 4, Lines 1-10). The Paul *et al.* patent further states that the disclosed compositions can be used for treating conditions facilitated by infections caused by pathogenic microorganisms such as *E. coli*, Salmonella, and Candida (See Column 16, Lines 21-26).

The Paul *et al.* patent does not make mention of the degree of polymerization of a dietary fiber.

The Van Loo *et al.* patent teaches a fructan-containing composition with an average degree of polymerization of 15 or higher (See Column 4, Lines 22-28; and Claim 1). The Van Loo *et al.* patent also discloses chicory inulin with an average degree of polymerization of about 25 (See Claim 18). The daily doses effective in providing prevention and treatment of colon cancer range from 0.01 to 2 g/kg of body weight (See Column 5, Lines 51-54).

One of ordinary skill in the art would be motivated to combine the two prior art references as they both broadly show that the administration of dietary fiber, such as inulin, is beneficial for the gastrointestinal health of a subject in need thereof. As the compositions in both prior art references have similar various effects which are known in the art to be beneficial to a subject, one of ordinary skill in the art would have a reasonable chance of success in combining the two references. Such effects include a reduction of intestinal transit time, a decrease of the

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intestinal pH, a bifidus stimulating activity in the colon, bulking of the stool, increase in stool frequency, and an improvement in lipid metabolism (See Paul *et al.*, Columns 2, 3, and 7-11; and Van Loo *et al.*, Column 2). Thus, the instantly claimed invention is *prima facie* obvious.

### **(10) Response to Argument**

#### **A. Disclosure of the prior art**

The applicant asserts that the prior art does not teach the instantly disclosed invention, and in support of this assertion, the applicant points out that the prior art does not teach or suggest the treatment of infections caused by an invasion of the lymph or the blood stream by pathogenic bacteria, nor does it teach the administration of a composition consisting essentially of an effective amount of inulin and/or oligofructose.

However, the instant claims are far broader than the applicant's own characterization. Claims 20 and 37 are drawn to methods of treating infections, where the nature of recited infection is not specified at the beginning of the claim. Therefore, in the view of the examiner, the gastrointestinal infections disclosed in the Paul *et al.* reference is not excluded by this claim language.

The methods of Claims 20, 27 and 37 are all characterized by open claim language, embodied by the use of the transitional phrase "comprising". Seen in light of the unspecified nature of the infections recited at the beginning of Claims 20 and 37, infections other than those caused by an invasion of the blood stream or lymph by pathogens appear to be encompassed by the scope of the instant claims.

Furthermore, the open claim language in the independent claims allows for the administration of additional substances to a patient. Although the primary method step recited in

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the independent method claims is the administration of a composition consisting or consisting essentially of an effective amount of inulin and/or oligofructose, it is the view of the examiner that the open scope of the instantly claimed methods do not necessarily exclude the administration of other substances such as beneficial bacteria or immunoglobulin as disclosed in the prior art, as pointed out by the applicant.

The way in which the applicant has characterized the instantly claimed invention also raises questions that have not yet been satisfactorily resolved. Throughout the prosecution of this case, the applicant has sought to distinguish the instantly claimed invention from what has been disclosed by the prior art by characterizing the types of infections treated by prior art methods as being patentably distinct from those intended to be treated by the instantly claimed invention. The applicant has characterized the types of infections treated by prior art methods as being a "local infection in the gastrointestinal tract" (see middle of the last paragraph on Page 9 of the applicant's brief) and states that this is patentably distinct from those infections caused by an invasion of the lymph or the blood stream by pathogenic bacteria.

Given that the gastrointestinal tract passes nutrients extracted from food into the blood stream primarily at the large and small intestines, it is unclear how an infection of the gastrointestinal system would not affect the blood stream to some extent. The degree to which a pathogen is present in the blood stream or the lymph to fall under what the applicant has termed an "invasion" of such has not been made clear by the applicant. It is unclear if the claims require that the recited pathogens occupy the entire circulatory or lymphatic systems in order to fall under the intended definition of these terms or of only a portion of these systems may be

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occupied. In the case of the latter, the question of precisely how much of these systems must be occupied by bacteria also remains unanswered.

Certain bacteria such as Salmonella are well known to cause severe infections by the ingestion of tainted food by a patient, which is naturally introduced to the body by way of the gastrointestinal system. In such a case, it is therefore difficult to draw the line of where Salmonella poisoning of the gastrointestinal tract is patentably distinct from Salmonella poisoning of the blood stream or the lymph. Because of such lingering issues, the examiner has chosen to maintain the prior art rejection of record.

#### B. Motivation to combine references

The applicant has argued against the combination of references, stating that there is no proper motivation to combine them. In the view of the examiner, Van Loo has shown that chicory inulin with an average degree of polymerization of about 25 is effective in promoting gastrointestinal health. That the particular application of the Van Loo reference is directed to the treatment of colon cancer is not seen by the examiner in detracting from its suitability as prior art, since both prior art references desire the same beneficial characteristics from dietary fiber that is administered to a subject in need thereof. Such characteristics include a reduction of intestinal transit time, a decrease of the intestinal pH, a bifidus stimulating activity in the colon, bulking of the stool, increase in stool frequency, and an improvement in lipid metabolism (See Paul *et al.*, Columns 2, 3, and 7-11; and Van Loo *et al.*, Column 2). Therefore, it is the position of the examiner that the Van Loo provides proper guidance to one of ordinary skill in the art in the selection of a particular type of inulin to administer to a patient.

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C. Reasonable expectation of success

The Paul *et al.* and Van Loo *et al.* reference both describe methods for the promotion of gastrointestinal health through the administration of particular dietary fibers such as inulin. The examiner therefore sees the references as being within the same field of endeavor, such that one of ordinary skill in the art would have a reasonable expectation of success of modifying the Paul *et al.* reference in view of the Van Loo *et al.* reference.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

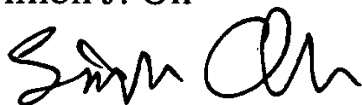
**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

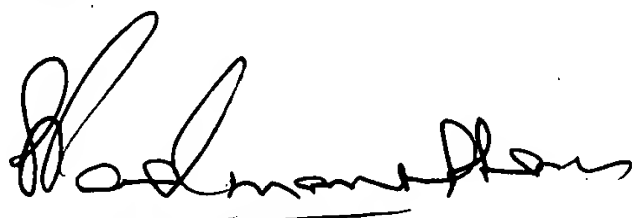
For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

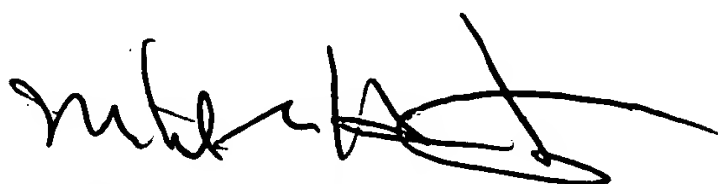
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